REMARKS

In the Office Action, claims 1-6 and 19-22 are rejected under 35 U.S.C. §112, second paragraph; and 1-12 and 19-22 are rejected under 35 U.S.C. §103. Applicants believe that the rejections are improper for the reasons set forth below.

In the Office Action, claims 1-6 and 19-22 are rejected under 35 U.S.C. §112, second paragraph. The Patent Office asserts that the claim term "typical amount" is allegedly indefinite. Applicants believe that this claim term is clear and definite in scope and meaning as defined in the claims and further supported in the specification.

Of the claims at issue, claims 1 and 19 are the sole independent claims and thus the remaining claims at issue depend from either claim 1 or claim 19. Independent claims 1 and 19 each relate to methods for delivering a medicament to an individual. Each claim recites, in part, providing a chewing gum that includes gum ingredients wherein the chewing gum includes less than the typical amount of medicament that is swallowed by the individual to achieve an effect as supported in the specification.

For example, the specification provides that less medicament or agent can be placed in the chewing gum than is typically orally administered (e.g., swallowed) to an individual to achieve an effect. See, specification, page 8, lines 3-7. Further, the specification provides that most orally administered drugs (e.g., medicaments) are in the form of tablets or capsules. See, specification, page 2, lines 19. Indeed, Applicants conducted an experiment to compare the caffeine delivery effects between chewing gum pieces with 50 mg of caffeine made pursuant to an embodiment of the present invention and chewable No-Doz® tablets with 100 mg of caffeine. See, specification, Experiment No. 2, beginning on page 16. In view of same, one skilled in the art would recognize that the chewing gum as claimed includes an amount of medicament, such as caffeine, that is less than an amount of the same medicament as swallowed, such as via oral administration in the form of a tablet or capsule. Therefore, Applicants believe that the claimed invention as defined in claims 1-6 and 19-22 is definite in scope and meaning and thus complies with 35 U.S.C. §112, ¶2.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-12 and 19-22 are rejected under 35 U.S.C. §103. More specifically, claims 1-4, 6-11, 19, 20 and 22 are rejected in view U.S. Patent No. 5,013,716 ("*Cherukuri*"); claims 5, 12 and 21 are rejected in view of *Cherukuri*; and claims 1, 7 and 19 are

rejected in view of *Cherukuri* and U.S. Patent No. 5,922,347 ("*Hausler*"). Applicants believe that the obviousness rejections are improper.

Of the pending claims at issue, claims 1, 7 and 19 are the sole independent claims. Claims 1 and 19 relate to methods for delivering a medicament to an individual as discussed above. Claims 1 and 19 each recite, in part, providing a chewing gum that includes ingredients and at least one medicament wherein the medicament and the ingredients are uniformly distributed throughout and wherein the chewing gum includes less than a typical amount of medicament that is swallowed by the individual to achieve an effect. Claim 1 further recites chewing the chewing gum to cause the medicament to be released from the chewing gum into the buccal cavity of the individual; and continuing to chew the chewing gum thereby creating a fluid pressure, thus causing the medicament to enter the systemic system of the individual through an oral mucosa of the individual. Claim 19 further recites that the chewing gum is chewed for at least 2 minutes in a buccal cavity of the individual.

Claim 7 relates to a method for reducing the amount of agent necessary to achieve an effect on an individual as compared to a typical agent that is swallowed. The method includes providing a chewing gum with less than the typical amount of agent that is swallowed by the individual to achieve the effect; chewing the chewing gum; and continuing to chew the chewing gum, thus forcing the agent through an oral mucosa contained in a buccal cavity of the individual.

In contrast, Applicants believe that the cited art, even if combinable, fails to disclose or suggest at least a number of features of the claimed invention. For example, the *Cherukuri* reference is deficient with respect to the medicament delivery features as claimed. At the outset, the Patent Office even admits that *Cherukuri* fails to teach chewing and continuing to chew the chewing gum, thus causing the medicament to absorb through the oral cavity as claimed. Further, claims 2 and 19 recite that the chewing gum is chewed for at least 2 minutes; and claim 3 further recites that the chewing gum creates a saliva content of medicament of approximately 1700 ppm to about 4400 ppm. Nowhere does *Cherukuri* disclose same as the Patent Office further admits. Moreover, nowhere does *Cherukuri* suggest the medicament delivery features as claimed contrary to the Patent Office's position.

Indeed, the clear emphasis of *Cherukuri* relates to masking unpleasant taste in ingestible products and not drug delivery, let alone drug delivery from chewing gums. See, *Cherukuri*, col.

3, lines 38-48. For example, *Cherukuri* provides that a taste masking agent can be applied to a laundry list of medicament drugs (See, column 6) or separately to a laundry list of different types of gums (See, columns 8-10). But, nowhere does *Cherukuri* suggest a chewing gum with a medicament that can be chewed and continued to chew to provide an effective delivery of the medicament to an individual chewing same as required by the claimed invention.

Moreover, *Cherukuri* effectively teaches away from chewing and continuing to chew a chewing gum that includes a medicament less than a typical amount of the same medicament as swallowed, such as in tablet or capsule form, as required by the claimed invention. *Cherukuri* merely provides that the medicament can be administered in physical forms, such as free forms, encapsulated forms or mixtures thereof, in ordinary dosage amounts. See, *Cherukuri*, col. 7, lines 3-17. As previously discussed, Applicants have found that less medicament or agent can be placed in the chewing gum than is typically orally administered to an individual to achieve an effect and the same bioequivalence can be achieved. In fact, Applicants have found that in certain instances, for at least certain drugs and agents, the administration of the medicament or agent using chewing gum through the buccal cavity can provide an increased effect even as compared to parenteral administration. See, specification, page 8, lines 2-7. Based on at least these reasons, one skilled in the art would recognize that *Cherukuri*, on its own, is clearly deficient with respect to the claimed invention.

Further, Applicants do not believe that *Hausler*, even if combinable, can remedy the deficiencies of *Cherukuri*. The Patent Office merely relies on *Hausler* for its alleged teachings regarding a stable chewing gum formulation that includes an active drug. Contrary to the Patent Office's position, this is not sufficient in scope to overcome *Cherukuri*'s deficiencies directed to the medicament delivery features as claimed, such as chewing and continuing to chew a chewing gum that includes a medicament to facilitate medicament delivery to an individual chewing same wherein the chewing gum includes less than a typical amount of the medicament as swallowed. What the Patent Office has done is to rely on hindsight reasoning in support of the obviousness rejection in view of *Hausler* and *Cherukuri*. Again, *Cherukuri* effectively teaches away form the claimed invention. Clearly, this is not proper. Thus, Applicants do not believe that one skilled in the art would be inclined to modify *Cherukuri* in view of *Hausler* to arrive at the claimed invention.

Based on at least these reasons, Applicants believe that the cited art is deficient with respect to the claimed invention. Therefore, Applicants respectfully submit that the cited art, alone or even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the patent application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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